REMARKS

Applicants submit this Response to the Non-final Office Action dated September 30, 2008. Claims 1, 15 and 18 have been amended. The amendments do not add new matter. Support for these amendments are found at least at page 12, lines 15 to page 13, line 2 of the application as filed. Applicants believe no fee is due in connection with this response, however, please charge Deposit Account No. 02-1818 for any amount that may be due.

In the Office Action, Claim 15 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite. In response, Applicants have amended Claim 15 to provide antecedent basis for every component mentioned after the preamble. Moreover, Applicants have removed all occurrences of the claim language "providing for" from Claim 15. These amendments are not meant, in any way, to overcome the art of record or disclose any subject matter with regard to same. As amended, Applicants submit that Claim 15 provides proper antecedent basis for all elements of the claim, recites actual method steps, and particularly points out what components are being utilized in the claim. Accordingly, Applicants respectfully submit that Claim 15 is properly definite under 35 U.S.C. §112, second paragraph, and request that the rejection be withdrawn.

In the Office Action, Claims 1 to 9, 11, 13 to 21 and 23 to 25 were rejected under 35 U.S.C. §102(e) as being anticipated by US Patent Publication No. 2002/0038392 to De La Huerga ("*De La Huerga*"); Claim 10 was rejected under 35 U.S.C. §103(a) as being unpatentable over *De La Huerga* further in view of Examiner's Official Notice; and Claims 12, 22, 26 and 28 were rejected under 35 U.S.C. 103(a) as being unpatentable over *De La Huerga* in view of US Patent Publication No. 2003/0105806 to Gayle et al. ("*Gayle*"). Applicants respectfully traverse these rejections for at least the reasons provided below.

Regarding the anticipation rejection of 1 to 9, 11, 13 to 21 and 23 to 25, *De La Huerga* fails to disclose or suggest a first central computer having a first database and a second central computer having a second database, wherein the first database is a subset of the second database as required, in part, by amended independent Claim 1. *De La Huerga* also fails to disclose or suggest receiving second data from a second database in a second central computer and from a secure connection and retrieving first data from a first database, which is a subset of the second database as required, in part, by amended independent Claim 15. *De La Huerga* further fails to

disclose or suggest a central validation computer having a validation database and a second central computer having a second database, wherein the validation database is a subset of the second database as required, in part, by independent Claim 18.

Applicants have found that a cost-effective integration of medical devices 120 or other devices and functionality with the hospital information systems in a first central computer 109 and a second central computer 108a is provided by isolating a subset of the total data of second computer 108a in a validated part of the system. In this context, the validated part of the system is located in the first central computer 109. This subset is isolated and located in the validated part of the system, within the first central computer 109, with the remaining portion of the overall data being maintained in a non-validated portion of the system, specifically within the second central computer 108a. See, specification, page 12, line 15 to page 13, line 2. Figure 3 illustrates the configuration between medical devices 120, first central computer 109 and second central computer 108a.
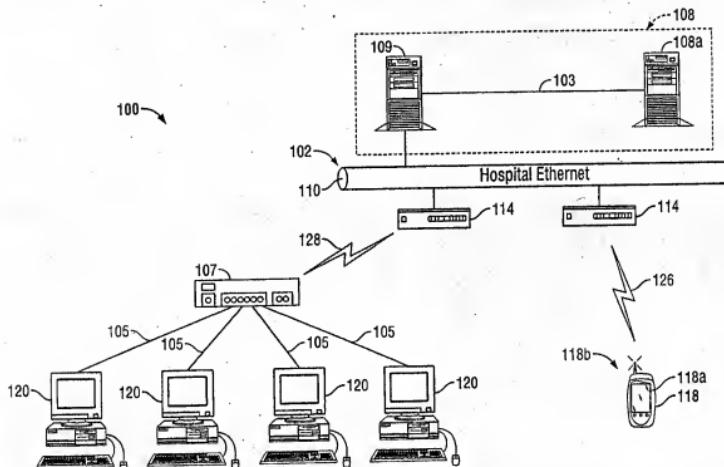

FIG. 3

By localizing a subset of the database, such as the patient safety-specific data at the first central computer, the cost of system development is streamlined, and integration with third-party

non-validated systems and the respective data and information therein is made both increasingly time and cost effective. See, specification, page 13, lines 17 to 20.

In contrast to independent Claim 1, 15 and 18, *De La Huerga* fails to teach a first computer having a database containing a subset of a second computer's database. Instead, *De La Huerga* teaches that by tying all system components together by control by a single controller 260, a coherent and easy to administer IV delivery protocol can be facilitated where the likelihood of inadvertent or malicious mismedication can be reduced. See, *De La Huerga*, page 16, paragraph [0196]. Therefore, rather than teach a first and second computer each with specific databases, one being the subset of the other, *De La Huerga* teaches a single controller imparting all instructions and performing all validations necessary. See, *De La Huerga*, page 16, paragraph [0200] to [0202]. Therefore, by using controller 260, *De La Huerga* fails to disclose or suggest a first and second computer with the first computer having its own database that is a subset of the second database of the second computer.

De La Huerga also fails to teach the second central computer sending data from the second database to the first central computer, and the first central computer sending data to the user interface as required by dependent Claims 8 and 9. Instead, *De La Huerga* teaches a single controller for imparting all instructions and performing all validations necessary, as described in detail above. The Office Action asserts that *De La Huerga* meets the data communication between first and second central computers by communication between <u>the interface and the first computer</u>. However, Claims 8 and 9 do not recite interaction with the interface during the communication between first and second central computers.

De La Huerga further fails to teach a system wherein the medical device and the user interface do not communicate directly with the second central computer as required by dependent Claims 16 and 20. Similarly, *De La Huerga* fails to disclose or suggest sending the second data (from the second central computer) to the user interface from the first central computer. Instead, Figure 26 of *De La Huerga* illustrates <u>direct communication</u> between controller 260 and pump 100a and associated interface through communication channel 255.

Regarding independent Claim 24, *De La Huerga* also fails to disclose or suggest a central validation portion of a central computer having a validation portion of a database and a second non-validation portion of the central computer having a second non-validation portion of the database, wherein the user interface can receive data from the second non-validation portion of

the database through the central validation portion of the central computer. As disclosed in the specification, a central computer can have at least two environments including a validated environment and a non-validated environment separated by a logical separation, firewall, or emulation software that emulates multiple environments on the same server. A single central computer can have a first and second server separated by a firewall with the first server housing the validation portion and the second server housing the non-validation portion. See specification, page 15, lines 1 to 21.

By contrast, *De La Huerga* fails to teach or suggest a single central computer having both a validation and non-validation portion. *De La Huerga* teaches use of a local controller 260 and a remote server 630/database 632. The Office Action asserts that the controller serves as the central validation portion while the server/database serves the non-validation portion. However, neither of these components individually possesses both a validation and non-validation portion of the component database. See, Office Action, page 13, #28. Moreover, nowhere does *De La Huerga* teach or suggest that these components are part of a single central computer or are even capable of being part of a single central computer. As stated above, the central computer of the present claims can have at least two environments including a validated environment and a non-validated environment separated by a logical separation, firewall, or emulation software that emulates multiple environments on the same server. A single central computer can have a first and second server separated by a firewall with the first server housing the validation portion and the second server housing the non-validation portion. See specification, page 15, lines 1 to 21. *De La Huerga* does not appear to suggest that either the controller or the server/database have the capability to operate both a validated and non-validated environment or both a validated server and non-validated server. Applicants accordingly respectfully submit that *De La Huerga* fails to teach a "single central computer" having both a central validation portion and a non-validation portion.

De La Huerga also teaches that controller 260, a local component, can access medication information via network 272 from a hospital computer system 630 and database 632, which are remote components. *De La Huerga* teaches the "local" nature of the controller by emphasizing the need to minimize the possibility of a patient obtaining the wrong patient's ID by limiting the signal transmission power of controller 260 to allow communication over only short distances. See, *De La Huerga*, page 16, paragraph [0200]. In contrast to the local controller 260, *De La*

Huerga also teaches that server 630 is a "remote server." See, *De La Huerga*, page 22, paragraph [0255]. Figure 31 of *De La Huerga* illustrates the physical separation between controller 260 and server 630/database 632 and the fact that there is no "central computer" housing these components.
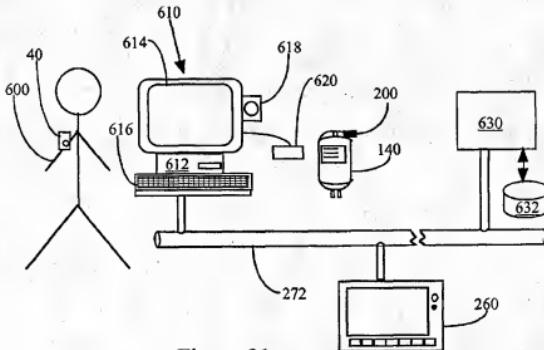

Figure 31

For at least each of the above reasons, Applicants respectfully submit that *De La Huerga* is deficient with respect to rejected Claims 1 to 9, 11, 13 to 21 and 23 to 25.

Regarding the rejection of Claim 10 as obvious over *De La Huerga* in view of Official Notice, Applicants respectfully submit that Claim 10 is in condition for allowance for the same reasons as independent Claim 1. Regarding the Official Notice, Applicants respectfully traverse and do not agree that connecting medical devices to computers wirelessly was common, old, and well known to someone of ordinary skill at the time the invention was made. Applicants note that the Office Action does not include any evidence to support the Official Notice. Regarding the obviousness rejection of Claims 12, 22, 26 and 28 in view of *De La Huerga* and *Gayle*, Applicants submit that Claims 12, 22, 26 and 28 are in condition for allowance for the same reasons as independent Claims 1, 18 and 24.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

BELL, BOYD & LLOYD LLP
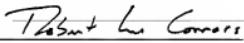
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